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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,327	12/03/2003	John Kirchgeorg	LIFE02WAB	5961

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	PAPER NUMBER
3766	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,327	KIRCHGEORG ET AL.	
	Examiner	Art Unit	
	Kennedy J. Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14 and 16-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14 and 16-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 11, 14, 16-21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold, Jr. (Pat. No. 4,060,079) in view of Hood et al. (Pat. No. 5,975,081).

Regarding claim 11, Reinhold, Jr. discloses a multi-component emergency medical system (see col. 1, lines 4-7) of a size and weight which can easily be carried by a single hand (see col. 2, lines 2-7, col. 7, lines 7-15, etc.) comprising: a breathable oxygen delivery system 76; a defibrillation system (see col. 3, lines 11-20); at least one

measurement system (again reference is made to col. 3, lines 11-20); and a unitary casing (oxygen container supporting assembly 16 and/or overall frame structure) for housing said oxygen delivery system, said defibrillation system and said measurement system (see for example col. 7, lines 30-49); the cumulative size and weight of the unitary casing, oxygen delivery system, defibrillation system, and measurement system such that the unitary casing, when housing the oxygen delivery system, defibrillation system and measurement system can easily be carried by a single hand (see col. 2, lines 2-7, col. 7, lines 7-15, etc.).

While Reinhold, Jr. does not elaborate on the use of a measurement system(s) for measuring at least one of blood or gas content, saturation, affinity or perfusion, the crux of the invention is to provide emergency heart-lung resuscitation. Those of ordinary skill in the emergency heart-lung resuscitation arts would have recognized the obviousness of including at least one such monitor in the system of Reinhold, Jr., because it is well-known that knowledge of blood or gas content, oxygen saturation, etc., is vitally important to proper emergency care and early diagnosis of patient condition. Knowledge of low oxygen saturation, for example, may necessitate emergency CPR and/or defibrillation procedures in order to provide the victim with adequate oxygen supply.

In any event, and independently of the above reasoning, Hood et al. additionally disclose a related emergency medical system that may include a variety of sensors including an oxygen saturation sensor, carbon dioxide sensor, etc. (note for example col. 3, lines 43-52 and col. 5, lines 55-62). It is taught that such equipment is crucial to

providing timely and proper emergency treatment during the "golden hour" –the time during which a patient's chances for survival are greatly enhanced if proper treatment can be immediately provided (see col. 1, lines 12-52). Given that both the Reinhold, Jr. and Hood et al. inventions are concerned with emergency medical treatment and have similar functioning, those of ordinary skill in the art desiring to provide immediate treatment in order to enhance the victim's chances for survival, would have seen the obviousness of including this well-known piece of medical diagnostic equipment in the system of Reinhold, Jr..

Regarding claim 14, while Reinhold, Jr. does not elaborate on the specific type of defibrillator system used, the examiner had taken Official Notice in the previous Office Action that AEDs are well-known portable and standard emergency equipment (attention is drawn to the applicants' own patent specification col. 1, lines 20-35). Automatic systems are especially useful in high stress emergency situations where operator error may severely affect the survivability of the patient. Said systems aid the caregiver by relieving the burden and responsibility of decision making, and have proven reliability and effectiveness in the field. As this Notice was not traversed, the feature is now considered admitted prior art.

Regarding claim 18 and claims with similar limitations, Reinhold Jr. does not discuss the use of a prompting system for directing a user through a protocol employing the oxygen delivery system and at least one measurement system. Hood et al., however, disclose a communications system 817 with microphone and speaker for communicating information and instructions from trained medical personal to the control

circuit and local care giver (see for example the text abridging cols. 22 and 23). Hood et al. also teach that the control circuit can be used to train emergency personnel in the operation of the device (see col. 23, lines 42-49). Directing a novice user through a protocol is a standard training tactic to ensure that the user is performing the correct procedure and to ensure that the user has confidence in using the equipment. Such prompting systems are a well-known and desirable technique in the medical arts to aid the rescuer in high stress emergency situations where human error may lead to disastrous consequences (in the same manner that one calling 9-1-1 may get prompts, instructions or assistance from a remote center staffed by personnel with superior medical training). Such systems are commonplace in emergency treatment devices such as the AED. To implement similar techniques to improve related emergency systems in order to provide the most effective treatment and eliminate operator error would have therefore been considered obvious to those of ordinary skill in the art.

Regarding claim 19 (with similar comments applying to claims 20, 24 and 25), while Reinhold Jr. does not discuss the use of a control processor for moderating the prompting system to direct the user based on feedback from at least one measurement system, the courts have indicated that the automation of a manual activity to accomplish the same result is not sufficient to distinguish over the prior art (see *In re Venner*, 262 F. 2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)). Here the machine is merely replacing the actions of the physician. For example, a physician or paramedic detecting low blood oxygen level would likely initiate oxygen delivery or other appropriate therapy, or in the very least, direct those with access to the treatment system on the proper procedure for

doing so. The applicants' in fact state that such protocols for the coordination of oximetry, oxygen delivery, and defibrillation are known in the medical arts (col. 3, lines 54-57). Furthermore, such prompting systems for emergency equipment in general are old and well-known in the art. Hood et al., for example, teaches that a verbal communication system may be employed to regulate operation of the field device to improve effectiveness of treatment. Official Notice was taken in a previous Office Action that AED devices, for example, commonly provide on-screen or voice command instructions (attention is directed to col. 1, lines 20-28, col. 3, lines 44-54 and the text abridging cols. 3 and 4 of the applicants' 497 patent) for proper placement of electrodes, shock procedure, and safety warnings in an effort to lessen the chances for human error in high stress situations. It would be reasonable to expect similar beneficial and predictable results for other emergency equipment often used in locations remote from primary care centers. To include a prompting system to direct an operator on proper use of the oxygen delivery system based on the results of diagnostic measurements would have therefore been considered a matter of obvious design. As the Official Notice was not traversed, this feature is now considered to be admitted prior art.

Regarding claims 21 and 26, Reinhold Jr. discloses that a wide variety of monitors and therapy devices (e.g., defibrillator) may be incorporated into the system (see for example col. 3, lines 11-21). While the use of a display *per se* is not discussed, those of ordinary skill in the art would have readily understood said monitoring and therapy equipment to include displays as is old and well-known in the medical arts. Hood et al., for example, disclose a related system wherein displays are employed to

convey information to the medical technician/user (see for example displays 84, 88, 25, etc.). Clearly the use of a display to convey vital information to caregivers on patient condition is crucial to providing adequate and effective treatment. As such, the inclusion of a display system would have been considered blatantly obvious to those of ordinary skill in the medical treatment arts.

4. Claims 22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhold Jr. and Hood et al. in view of Dudley (Pat. No. 3,905,363) or Sundblom et al. (Pat. No. 3,820,566).

Reinhold Jr. does not discuss means for controlling the oxygen delivery system, for switching or prompting a user to switch said oxygen delivery system between a variable flow rate/pressure cyclic ventilator mode and a fixed flow rate mode. Dudley teaches the importance of utilizing separate ventilator modes of operation depending on the patient's needs, where one mode intrinsically involves variable flow rates to assist the patient's breathing based on demand and the other mode involves fixed flow rates without feedback to completely control the intake of fluid when a patient is not breathing (see for example cols. 1 and 2). Since the ability to provide for different modes of operation to account for the patient's condition is a decided advantage and well-known in the art, those of ordinary skill looking to enhance the versatility and thus the effectiveness of treatment, would have considered incorporation of the means for modal control into the system defined by Reinhold Jr. and Hood et al. to be obvious.

Sundblom et al. disclose a versatile, compact ventilator and teach that prior to their invention, users had little, if any, opportunity to adjust flow rates --flow rates were

essentially always fixed (see col. 1, lines 26-43). Sundblom et al. also teach in the same section that because it is desirable to have a large initial flow at the beginning of the inspiratory phase with diminished flow towards the end of the phase, the ability to provide variable flow rates is advantageous. As stated in the text abridging columns 2 and 3, flow and pressure can be automatically adjusted or manually set. Given the recognized need to enable various flow/pressure modes depending on the particular situation at hand and given the disclosure that such control affords the user a versatile and effective way to treat the patient, those of ordinary skill in the art would have seen the obviousness of incorporating flow rate/pressure modal control into the system defined by Reinhold Jr. and Hood et al..

Response to Arguments

5. Applicant's arguments filed July 27, 2009 have been fully considered but they are not persuasive.

The crux of the applicant's arguments center on the claim recitation, "...can easily be carried with a single hand." The applicant argues that the device described in the Reinhold Jr. patent cannot be easily carried with a single hand regardless of the stature and strength of the individual transporting the device because it is too heavy (estimated by the applicant to be upwards of 80 lbs).

The examiner responds that the Reinhold patent explicitly teaches that the design of his multi-component medical system (which includes the frame structure together with the other treatment components) enables it to be manually *carried* by a *single* attendant (see col. 1, line 53- col. 2, line 7). Reinhold discloses that it is desirable

to limit the size and weight of the system in order to overcome many of the disadvantages of traditional "ambulance stretchers" which are often restricted in movement (see col. 1, lines 24-52), or which require two individuals to carry the device (see col. 1, lines 12-23). While caster wheels may be added for assistance, such an addition hardly teaches away from the idea of enabling one to use a handle to transport the system, as suggested by the applicant. Such a feature would merely give the rescuer the option of rolling the device where convenient such as over a smooth surface, while allowing the device to be lifted over obstacles, up and down stairways, over rough terrain, etc., in order to reach the patient (see for example col. 7, lines 3-7). To suggest that Reinhold added the wheels because "...even Reinhold must have known that the fully laden device would weigh too much for someone to be able to carry with the handle 26..." (see page 9 of the Remarks), runs contrary to the stated goal of Reinhold –to provide a system that can be manually carried by an individual to locations previously inaccessible to prior art equipment such as wheeled stretchers.

Regarding the applicant's speculation that the weight of the Reinhold device with "E-size" oxygen cylinders would be on the order of at least 70 or more pounds, the examiner argues that the use of so-called "E cylinders" is not mandatory. Reinhold states that the cylinders *may* be E-size (see col. 7, lines 44-47). According to the applicant's evidence, cylinders for medical use range from A to E, with E being the largest (even larger "building supply" cylinders such as H-size are available but would clearly not be used for emergency applications such as presented by Reinhold). One of ordinary skill and reason in the art would have readily understood that the Reinhold

system was not limited to use with only E-size cylinders, but could encompass other medical oxygen container sizes dependent upon the application at hand. Reinhold further emphasizes that while the oxygen containers may be of conventional design, any other appropriate design would also be suitable, thus further highlighting to one of ordinary skill that the invention is not limited to conventional E-size cylinders (see col. 5, lines 57-68). The examiner would also argue that there is no requirement for the cylinders to be fully loaded all the time (in fact such a feat would be impossible since during use the cylinders would naturally lighten as they empty, making the system lighter once recollapsed for transport and storage). One can also argue that a single cylinder may be used without sacrificing functionality of the Reinhold system (an empty cylinder, for example, might be removed to permit refilling or replacement after returning from an emergency call).

The applicant states that KSR is not applicable to the present case because a prima facie case has not been established. The examiner contends that a prima facie case has indeed been established for all of the above reasons and subsequent reasoning below. Given the expressed desire by Reinhold to limit the size and weight of the system to allow a single individual to readily carry the device up and down stairs, through restricted pathways, etc., it would have been reasonable to expect that those of ordinary skill in the art would have at least found it obvious to try one of the known, conventional smaller medical oxygen A-D cylinders if a lighter system were needed for particularly difficult terrain or to allow a female responder to better manage the device. Lighter weight cylinders would predictably make the system even easier to handle.

Aside from KSR, even if one were to assume for the sake of argument that the Reinhold system is not easily carried by a single hand, it is well-recognized that making a device portable or movable, or changing the size and weight is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results (MPEP 2144.04). Here again, the use of lighter equipment or lighter materials to make the system easier to port would be considered an obvious solution to obtain the desired result set forth by Reinhold (i.e., to make the system lightweight and readily portable).

Regardless of the size of cylinder used, the fact still remains that Reinhold intended the entire system to be lightweight (see col. 3, lines 21-24) and hand carried by a single individual. Column 7, lines 3-15, for example, state that the minimized weight of the system allows the contraption to be *readily* moved in its collapsed position through pathways not easily accessible to conventional stretchers. Further, given a suggested 22 inch overall width, single handle 26 (see Fig. 1) appears to be of a size that would permit only one hand to comfortably grasp it (much like the handle of a standard suitcase).

The evidence submitted by the applicant pertaining to baggage handler recommended weight guidelines cannot be readily applied to the current situation. It is safe to assume that baggage handlers typically are consistently and repetitively required to lift numerous heavy loads throughout the course of the day as airliners, buses, etc. are loaded and unloaded. By the end of a long day, muscle fatigue may set in causing loads that may have been easy to lift at the beginning of the shift, much more

difficult to handle. By contrast, emergency situations requiring a single individual to hand carry systems such as disclosed by Reinhold do not typically occur with such regularity and repetitiveness throughout the day. An emergency situation may only require the system to be briefly lifted off the curb and onto a street to reach the victim, or down/up a front stoop into or out of a house. The EMT would not be expected to regularly unload numerous litter units off the curb to treat one victim.

The assertion that a handle at the long end of the Reinhold device would require a person to lift the device to at least shoulder level is also not agreed with. As the examiner has previously argued, the frame of Reinhold allows one to conveniently grasp the system from any end. Even if one were limited to grasping the device only at the handle 26, unless one was abnormally short, lifting a three foot, five inch long device off the ground would not necessitate lifting the device to shoulder length.

What is considered easily carried by a single hand is subjective and depends on the physical capabilities of the individual lifter. The original specification does not appear to provide an explicit definition of the term “easily carried." The examiner does not agree with the applicant’s contention that firemen, paramedics, soldiers and the like would be no more capable than the average person at carrying the Reinhold device. Said professionals are required as a part of their job description to carry heavy equipment and thus must maintain a certain level of physical fitness to successfully perform their job. One would reasonably expect such people to be of above average fitness and strength. Furthermore, the claim does not require the system to be easily carried by a single hand of a person with “average” strength. All that is required is that it

be easily carried by a single hand. One can argue that an Olympic weightlifter, professional football player, or other similarly strength-trained athletes can easily lift at least 70 lbs off the ground with a single hand. There is further no requirement as to how long, how far, and how high the system must be lifted. As stated above, one can imagine a situation where the device only need be lifted off the curb and onto the street to treat an accident victim.

Moreover, the applicant is speculating on the overall weight of the system. Reinhold states that a commercial version of the product weighs less than 50 lbs without the oxygen container. The applicant infers that the actual weight sans oxygen would be on the order of 40 lbs or more or else the device would not be rugged enough to be able to support a patient during resuscitation with a chest compression device. Metal litters, however, can be very lightweight and rugged. Foldable, metal litters such as the well-known and widely used Stokes litter were in use as early as World War II with modified versions back then weighing as little as 20 pounds (http://med-dept.com/litters.php). It would be safe to assume that advances in materials and manufacturing techniques since the 1940's and up until the invention of Reinhold have made litters even more lightweight while preserving or even enhancing their requisite ruggedness. Given Reinhold's desire to develop a lightweight system that can be carried by a single individual over obstacles and the availability of known lightweight equipment (including lighter weight oxygen tanks as argued above), it would be reasonable to speculate that the weight of the overall system could just as likely be in a range of 50 to 60 pounds, making the examiner's arguments even more tenable.

Finally, the applicant's reference to prior prosecution history (specifically citing the former §103 rejection in view of Andrews et al.) as a means to argue against the present rejection is a moot point since the merits of the current rejection are at issue.

In summary, it is the examiner's position that the phrase, "...can easily be carried with a single hand," is subjective and thus open to interpretation. Reinhold intentionally has designed his system to be lightweight and readily carried over obstacles by a single person. A single handle is accordingly provided. Artisans of ordinary skill in the art striving to achieve the design goals of Reinhold would have considered any modification to make the Reinhold system lighter, smaller, more compact, etc., obvious for all of the above stated reasons. In short, the examiner believes that a prima facie case of obviousness has indeed been established, with the burden of proof shifted to the applicant to prove otherwise.

Reissue Applications

6. The applicants are reminded that any amendment in response to this rejection must be accompanied by a supplemental oath/declaration.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/

Primary Examiner, Art Unit 3766

KJS
September 15, 2009